



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Koike *et al.*

Appl. No.: 10/662,820

Filed: September 16, 2003

For: **Quinone-based Therapeutic Agent  
for Hepatopathy**

Confirmation No.: 1102

Art Unit: To Be Assigned

Examiner: To Be Assigned

Atty. Docket: 1089.0410001

**Information Disclosure Statement**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

Listed on accompanying Form PTO/SB/08a and PTO/SB/08b are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO forms based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may

not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

Applicants have checked the appropriate boxes below.

- ☐ 1. Statement under 37 C.F.R. 1.704(d). Each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart application and this communication was not received by any individual designated in 37 C.F.R. § 1.56(c) more than thirty days prior to the filing of this information disclosure statement.
- ☒ 2. Filing under 37 C.F.R. § 1.97(b). This Information Disclosure Statement is being filed within three months of the date of filing of a national application other than a continued prosecution application (CPA), OR within three months of the date of entry of the national stage as set forth in 37 C.F.R. § 1.491 in an international application, OR before the mailing date of a first Office Action on the merits OR before the mailing of a first Office Action after the filing of a request for continued examination under 37 C.F.R. § 1.114. No statement or fee is required.
- ☐ 3. Filing under 37 C.F.R. § 1.97(c). This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final

Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application.

- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ c. Attached is our PTO-2038 Credit Card Payment Form in the amount of \$\_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p).
- ☐ 4. Filing under 37 C.F.R. § 1.97(d) This Information Disclosure Statement is being filed more than three months after the U.S. filing date and after the mailing date of a Final Rejection or Notice of Allowance, but before payment of the Issue Fee. Enclosed find our PTO-2038 Credit Card Payment Form in the amount of \$\_\_\_\_\_ in payment of the fee under 37 C.F.R. § 1.17(p); in addition:

- ☐ a. Statement under 37 C.F.R. § 1.97(e)(1). I hereby state that each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(1).
- ☐ b. Statement under 37 C.F.R. § 1.97(e)(2). I hereby state that no item of information in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing of this Information Disclosure Statement. 37 C.F.R. § 1.97(e)(2).
- ☐ 5. The document(s) was/were cited in a search report by a foreign patent office in a counterpart foreign application. Submission of an English language version of the search report that indicates the degree of relevance found by the foreign office is provided in satisfaction of the requirement for a concise explanation of relevance. 1138 OG 37, 38.
- ☒ 6. A concise explanation of the relevance of the non-English language documents AA1 and AB1 is provided by the English abstracts provided therewith. Further English translations of the relevant portions of documents AG2-AI2 are provided therewith.
- ☐ 7. Copies of the documents are submitted herewith.

- ☐ 8. Copies of the documents were cited by or submitted to the Office in an IDS that complies with 37 C.F.R. § 1.98(a)-(c) in Application No. \_\_\_\_\_, filed \_\_\_\_\_, which is relied upon for an earlier filing date under 35 U.S.C. § 120. Thus, copies of these documents are not attached. 37 C.F.R. § 1.98(d).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO/SB/08a and PTO/SB/08b and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Date: May 7, 2004

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~~Substitute for form 1449A/PTO~~

# INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet No.	1	of	2
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**Complete If Known**

Application Number	10/662,820
Filing Date	September 16, 2003
First Named Inventor	Koike <i>et al.</i>
Art Unit	To Be Assigned
Examiner Name	To Be Assigned
Attorney Docket Number	1089.041000171UM

[illegible]

**FOREIGN PATENT DOCUMENTS**

Examine r Initial s*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T e
		Country Code <sup>4</sup> Kind Code <sup>5</sup> (in known)				
	AA1	JP 06-305955	11-01-1994	Eisai Co. Ltd.		
	AB1	JP 63-185921 A	08-01-1988	Takeda Chem Ind. Ltd.		


**Examiner Signature**

Date  
Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M PEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>See Kind Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Transaction is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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Substitute for form 1449B/PTO		<b>Complete If Known</b>	
 <p><b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b></p> <p>(Use as many sheets as necessary)</p>		Application Number	10/662,820
		Filing Date	September 16, 2003
		First Named Inventor	Koike <i>et al.</i>
		Art Unit	To Be Assigned
		Examiner Name	To Be Assigned
Sheet 2	Of 2	Attorney Docket Number	1089.0410001/TUM

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date page(s), volume-issue number(s), publisher, city and/or country where published	T <sup>2</sup>
	AA2	"Comparison of Antitumor Activity of Vitamins K <sub>1</sub> , K <sub>2</sub> and K <sub>3</sub> on Human Tumor Cells By Two (MTT and SRB) Cell Viability Assays," Felicia Y. - H. Wu <i>et al.</i> , Life Sciences, Vol. 52 pp. 1797-1804, Pergamon Press 1993.	
	AB2	"Changes of Plasma Des-y-Carboxy Prothrombin Levels In Patients With Hepatocellular Carcinoma In Response to Vitamin K," Midori Furukawa <i>et al.</i> , Cancer, Vol. 69, Number 1, pp. 31-38, J.B. Lippincott Company, Philadelphia, January 1, 1992.	
	AC2	"DES-y-Carboxy Prothrombin As A Useful Predisposing Factor for the Development of Portal Venous Invasion in Patients with Hepatocellular Carcinoma," Yukihiro Koike <i>et al.</i> , Cancer, Vol. 91, Number 3, pp. 561-569, John Wiley & Sons, Inc., February 1, 2001.	
	AD2	"The Growth Inhibitory Effects of Vitamins K and Their Actions On Gene Expression," Ziqiu Wang <i>et al.</i> , Hepatology, Vol. 22, pp. 876-882, September 1995.	
	AE2	O'Neil, J.M. <i>et al.</i> , The Merck Index Thirteenth Edition, Merck & Co., Inc., 2001 pg. 1787, Item 10082 on Vitamin K.	
	AF2	Randomized Prospective Study of Prevention from Tumor Invasion Into Portal Vein In 120 Patients with Hepatocellular Carcinoma by Vitamin K Administration, <a href="http://ddw02.agora.com/planner/displayabstract.asp?presentationid=31">http://ddw02.agora.com/planner/displayabstract.asp?presentationid=31</a> , July 8, 2002.	
	AG2	38 <sup>th</sup> Annual Meeting of Liver Cancer Study Group of Japan, Item 110, p. 135, Inhibitory Effect of Vitamin K Injection Against the Recurrence of Hepatocellular Carcinoma, published on May 13, 2002	✓
	AH2	Japanese Journal of Gastroenterology, Vol. 99 Supplement, March 20, 2002, Item 308, A Clinical Study of the Effects of Vitamin K in Inhibiting Recurrence of Hepatocellular Carcinoma	✓
	AI2	ACTA Hepatologica Japonica, Vol. 43 Supplement (1) 2002, May 20, 2003, Item O-98, A Randomized Prospective Controlled Study by Vitamin K-II Injection for the Purpose of Preventing Portal Venous Invasion (PVI)	✓

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with M PEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Applicant's unique citation designation number (optional). <sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.

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